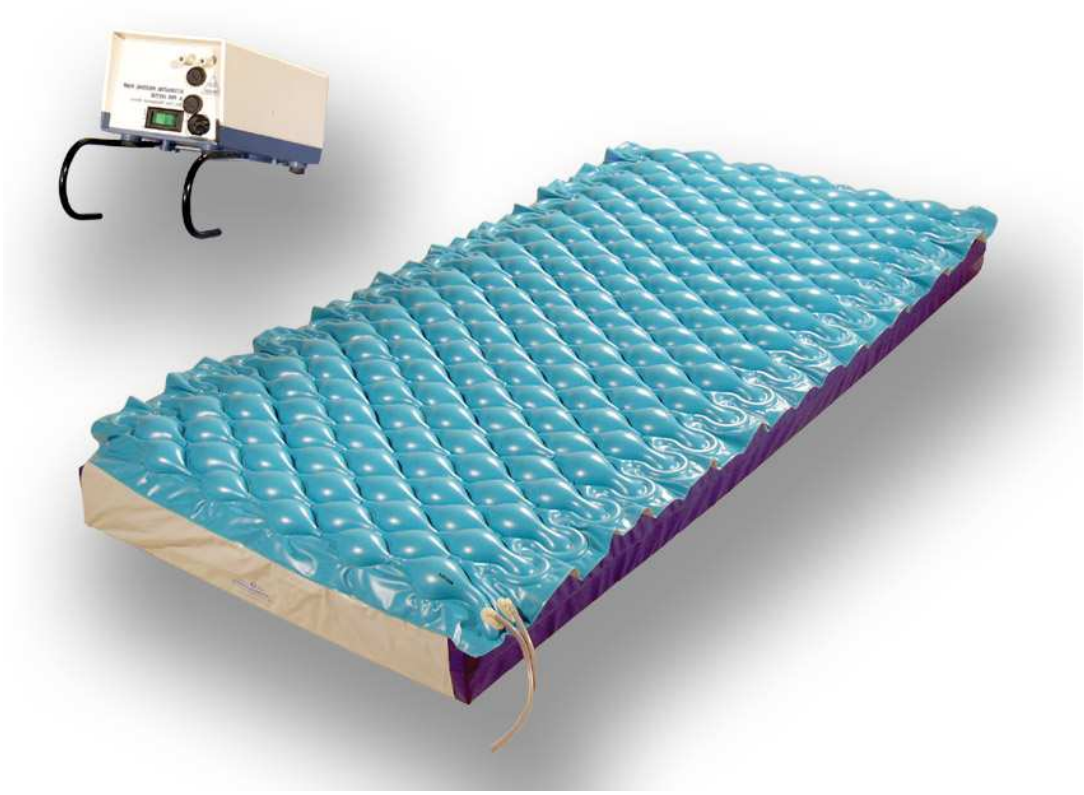
USER MANUAL AND TECHNICAL DESCRIPTION

CE

ProDerm 1

ACTIVE PRESSSURE RELIEVING MATTRESS SYSTEM



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LINET®

ProDerm 1
Active Pressure Relieving Mattress System

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Related links: www.linet.cz

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Contents

1	Introduction	4
2	Delivery	5
3	Safety Instructions	5
4	Conditions for Use	6
5	Technical Parameters	6
6	Mattress System Installation and Setting Up	7
7	Cleaning and Infection Control	8
8	Maintenance and Troubleshooting	9
9	Storage	9
10	Environmental Protection	10
11	Warranty and Service	12
12	Used Marks and Symbols	12
13	Contacts	12
A	Appendix I - Record of service checks and routine maintenance	13
B	Appendix II – ProDerm 1 Mattress System Handover Protocol	14

1 Introduction

Active Pressure Relieving Mattress System ProDerm 1 (*original title Mark Ie*), operated by LNT-09R0 Control Unit is a specialized Air Therapy Support Systems for prevention of pressure sores. The ProDerm 1 Overlay is designated for use in combination with common hospital mattress. It is an alternating system that employs durable shaped air tubes and control unit, which is designed for the purpose to achieve a good massage effect and blood circulation in the body tissue.

The mattress system is designed and manufactured in conformity with international standards EN 60601-1-2, EN 60601-1, EN ISO 10993. The product also meets all the requirements of Directive 93/42/EEC, standard technical requirements for medical devices and 89/336/EEC, including EMC.
The manufacturer operates under quality management systems certified in accordance with EN ISO 9001:2000 and EN ISO 13485:2000 Standards.

Prior to using this mattress system, it is important to familiarise yourselves with this manual. All operation and user servicing should be carried out in accordance with this manual!Any other operation being in discrepancy with the user manual or the purpose of the bed is carried out at the user's risk and the supplier shall not be liable for any possible damage or injury.
It is important to ensure the manual is available to the user throughout service life of the mattress system!

Warning:

- The supplier cannot be responsible for damages, injuries, accidents or casualties generated by virtue of incautious, neglectful or incorrect handling.
- The basic briefing of mattress handling will be guided by supplier or trained person.
- The Safety Instructions for mattress system operation and handling directions must be strictly observed.

2 Delivery

Mattress system is delivered in pasteboard packaging, the Control Unit is separated from Overlay. The whole consignment must be checked for completeness on delivery in accordance with the delivery note. The shipper and the supplier should be advised immediately of any defect or damage in writing.

3 Safety Instructions

- Prior to using the mattress system the carer should be familiarise themselves with the operation of the bed as detailed in this User Manual. All operations of the mattress system should be done in accordance with this Manual.
- Do not use the mattress system if any fault is found, especially faults, which might cause injury to a patient, staff or any third person, or damage to the mattress, bed or other surrounding equipment.
- Only fully trained and experienced Carers should be allowed to operate this mattress system.
- Prior to use the user should check that all functions are in order and bed has no faults.
- The mattress system can be used in background parameters stated in Conditions for use only.
- It is prohibited to use mattress system in patients with weight overlapping the limit stated in User Manual.
- Before cleaning or undertaking any maintenance always unplug the mains cable.
- The mattress system should not be used in an explosion hazard environment or in a presence of inflammable anaesthetics.
- Only approved Manufacturers spares should be used. If other supplier's parts are used, the manufacturer/supplier cannot be held responsible for any damage or injury.
- The Control Unit and mattress has to be protected against liquid penetration or open flame.
- Prevent the contact of mattress and sharp object or objects, which can cause damage of mattress.
- Do not place the heat source near to mattress system.
- Always connect the Main Unit to the prescribed and safe electric current source.

4 Conditions for Use

The mattress system should only be used in an internal environment where:	…the ambient temperature ranges from +10℃ to +40℃
	…the relative humidity ranges from 30% to 75%
	…the atm. pressure ranges from 700 to 1060 hPa

Any use outside these conditions must be discussed with the supplier!

5 Technical Parameters

Control Unit ProDerm 1

Model no.	LNT-09R0 FOR PRODERM 1
Dimensions	22 x 10 x 8,5 cm
Weight	1,6 kg
Supply	230 V AC, 50 Hz
Power Input	Max. 75W
Water and dust preventing	IPX0
Classification:	Class I
	Device of the BF type
Fuses parameters:	T1AH250V AC
Operating cycle:	Continuous
Pressure alternating interval	5 minutes

Overlay ProDerm 1

Model no.	
Dimensions	198 x 89 x 6 cm
Weight	2,5 kg
Material	PVC
Maximal weight of patient	**90 kgs**

In spite of the mattress system is designed in accordance with EN 60601-1-2 Standard (Medical electrical equipment. Part 1-2: General requirements for safety: Electromagnetic compatibility), sensitive medical devices could be influenced by the electromagnetic emission of the mattress Main Unit. It is necessary to deactivate the Control Unit for a duration of the measuring with these devices.

Indication
… patients with low risk of pressure sore development (that means patients with 20-25 points on extended Norton Pressure Sores Severity Scale)

Contraindications
… patients with higher risk of pressure sores development than the system is designed for.
… patients with unstable cervical fractures.
… patients with unconsolidated vertebral fractures.
… patients with weight overlapping maximum weight stated in Technical Parameters of the mattress system.

6 Mattress System Installation and Setting Up

1. In agreement with Delivery Note check the completeness of the delivery and check if there is any visible damage incurred by transport. Eventual inadequacies point out to Delivery Note and pass on to supplier.
2. Carefully read the User Manual.
3. Lay out the overlay directly onto the existing common mattress and ensure that the supply hoses are at the foot end of the bed. Secure the overlay to the mattress through the securing straps on the mattress.
4. Hang the Control Unit to the foot-board of the bed frame. Attach the air tubes connectors to socket on the left side panel of the Control Unit. Ensure that the air hoses are not wrapped or kinked under the mattress.
5. Carefully plug the power cord into a properly grounded power source. Turn on the master switch on the front panel.
6. The Control Unit should start to inflate the mattress.
7. After total inflation, which takes max. 20 minutes, put the lining freely onto the mattress.

Alternating Function: The Control Unit starts to alternate the pressure in Overlay cells in the 5 minutes time interval.

8. Ecologically liquidate the packaging.
9. Carefully save the User Manual.

Eventual inadequacies report immediately after delivery to the supplier of mattress system.

Maximum weight of patient is 90 kg.

Anti-decubitus effect of mattress system is lowered when any other than supine position of patient is used. Maximal recommended tilt of the backrest is 30°while the active mattress is used.

Inappropriately strained lining preclusive the preventive function of mattress system. Bed sheet should be put freely onto the overlay.

7 Cleaning and Infection Control

Overlay/Mattress

The Overlay/Mattress should be cleaned on the bed weekly using a damp soft cloth and mild detergent. Overlay/Mattress can be wiped over with a solution of sodium hypochlorite 1000ppm or any other non-phenolic germicidal solution.

While using disinfection and cleaning solutions take notice of following directions:

- Avoid highly alkaline or acid chemicals using (value should not exceed pH 6 up to 8)
- Do not use abrasive cleaning agents
- Do not use any chemicals containing any substance, which could change the structure and adherence of plastics (thinners like acetone, toluene, gasoline etc.)

Control Unit

Switch off the electrical supply to the Control Unit and disconnect the power cord from the main supply before cleaning and inspection !

The Control Unit should also be cleaned weekly using a damp soft cloth and mild detergent.
The Control Unit case is manufactured from ABS plastic. If the case is soiled the Control Unit can be wiped down with a sodium hypochlorite solution of 1000ppm or any EPA- approved hospital disinfectant.
(Do not use phenol based cleaning solutions)

Make sure the pump is completely dried before connect the power cord onto the power mains.

Use of improper detergents or disinfectants, non-observance of supplier's instructions regarding dosage and combinations with other agents, or faulty care of a mattress system may lead to damage, which the supplier cannot be responsible for.

8 Maintenance and Troubleshooting

It is recommended to order the inspection by supplier after every 6 months of using. This inspection includes the exchange of the Control Unit air filter.

Failures	Possible cause	Removal
Control Unit is not working	Wrong hose connection Blown fuse Control Unit defect	Check the connection Exchange the fuse 3. Contact the service dept.
Control Unit works, but the air does not blow	Defect on the air pump diaphragm Disconnected hoses Defect on inductor inside of the Control Unit	Contact the service dept. Plug in the hoses Contact the service dept.
The Overlay/Mattress is not inflated after one hour of master unit operating	The air escapes from cells Crashed or wrongly fixed incoming hoses	Check the cells 2. Check the hoses, contact the service dept.

In case of any major failure do not try to repair the Control Unit!
Do not open the Control Unit case! Contact the service dept. of Linet.

9 Storage

Before Storage check all parts of Mattress System and their functionality.

Control Unit:

- Check the power cord and plug for abrasions or excessive wear.
- Plug in the unit and verify that air flows from the units hose connection ports
- Place in plastic bag for storage and protect against liquid penetration.

Mattress:

- Check the air manifold for kinks or breaks.
- Disconnect the air feed tubes. All the air will now be expelled. Starting at the head end, the mattress can be rolled.
- Place in plastic bag of storage.

Conditions for storage environment are the same as for the operational environment

If any major fault or deficiency is found the mattress system must not be used and the manufacturer / service contractor must be contacted immediately.

10 Environmental Protection

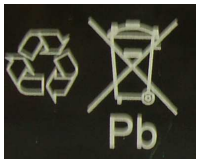
The company LINET, spol. s r.o. is aware of the necessity to protect the environment for future generations and therefore devotes great attention to the development, innovation – planning, production and use of such technology and materials that are environmentally friendly.

This product is constructed from materials that are environmentally friendly! The product does not contain dangerous substances based on cadmium, mercury, asbestos, PCB or CFC! The operational noise-level of the product meets the requirements for the protection of public health against undesirable noise and vibration in protected indoor building premises. Wooden parts used in the product are not made from exotic wood such as mahogany, jacaranda, ebony, teak, grenadil or santo, and do not come from the Amazonian rainforests or other virgin forests.

All waste packaging left over from when the product is made operational is marked in accordance with the legal regulations on packaging. Sort the waste packaging, which is left over once the product is made operational by following the graphic symbols and deliver it to a person authorised to further utilise it.

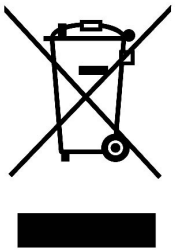
The product contains recyclable steel, plastic and electronic components – to optimise recycling once the operation of the product ends, separate the individual parts so that the raw materials from which the product is made can be put to further use (see CHART).

The product may contain lead accumulators (AKB) marked with this graphic symbol:
Once the service life of these accumulators ends, deliver them to a person authorised for recollection (you will not have to pay a recollection charge!).



The product is not designed for removal as part of communal waste!

Information for the users of electric and electronic equipment (see CHART):



This symbol on the product or accompanying documentation means that the electric or electronic components used (waste from electric and electronic equipment = OEEZ/WEEE) may not be disposed of (destroyed) together with communal waste. In order to correctly eliminate the entire product, deliver OEEZ/WEEE to the workplaces of firms specialised in this task, where they will be accepted free of charge.

By removing this product appropriately you will help preserve valuable natural resources and help prevent potential negative effects on the environment and human health, which could result from the incorrect destruction of waste. You can request further details from authorised environmental protection authorities, or the closest collection point for separated waste collection.

Fines may be imposed under national regulations if an incorrect procedure for waste removal is used.

Information for users about the removal of electric and electronic equipment in other countries outside the European Union:

The symbol shown above is valid only in the countries of the European Union. You can apply to your authorities or the equipment seller for detailed information about the correct way of removing separated OEEZ/WEEE (electric and electronic equipment) and lead accumulators.

Protect your health and the environment. Thank you.

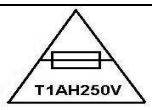
11 Warranty and Service

There is a **24 months warranty** granted for this mattress system commencing on the delivery date if there is no other stipulation in a sale agreement!

The warranty and after warranty service is done by the supplier or authorised service on a base of written authorisation confirming qualification for such activities. Respective authorisation is issued by a manufacturer.

12 Used Marks and Symbols

	Warning in User Manual
O	**Switched-out**

	**Fuse type (T1AH250V)**
I	**Switched-on**

13 Contacts

Your queries address to:

Tel.: +420 312 / 57 61 11
Fax: +420 312 / 52 26 68

Address: LINET spol. s r. o., Želevčice 5, 274 01 Slaný, Czech Republic
http://www.linet.cz, E-mail: info@linet.cz

A Appendix I - Record of service checks and routine maintenance

PURPOSE AND DESCRIPTION OF WORK	DATE	TECHNICIAN

B Appendix II – ProDerm 1 Mattress System Handover Protocol

Order No.:

Purchaser:

Model No.:

Supplier:

Handover date:

Serial No.:

I confirm, that the training of attending staff on the use of the mattress system has been completed.
Warranty period:

....

Date Stamp and signature of Supplier Stamp and signature of Purchaser

This handover protocol confirms the start of the warranty period.

Always quote order number or products in any communication with the supplier.

EC CONFORMITY DECLARATION

Date of issue: 14. 5. 2005

Conformity declaration issued by:

Commercial name	Linet spol. s r. o.
Registered address	Želevčice 5, 274 01 Slaný, Czech Republic
Reg. No.	00507814
Telephone	+420 312576111
Fax	+420 312522668
As the importer of the product - name (brand):	ProDerm
Producer:	Caremed Supply, Inc. 7 F, No. 2, Lane 235 Bao Chiao Rd., Xin Tien City, Taipei 231,Taiwan.
Variants of the product:	ProDerm 1, ProDerm 1 Plus, ProDerm 2, ProDerm 2 Plus, ProDerm 3, ProDerm 3 Plus, ProDerm 4, ProDerm 5
Description and function designation:	Active anti-decubitus mattress system with air pump
Classification of the product as the medical device:	**Class I** nonsterile, without measuring function

A) Declaration

- I declare that the said product is safe under the conditions of common use in compliance with the instructions and that measures have been taken to ensure the conformity of all the products brought to market with basic requirements of directives related thereto, stated in paragraph B.

B) Fulfilled technical requirements

- This product's characteristics comply with the technical parameters related to it and stated in MDD 93/42/EEC which stipulates the technical parameters for healthcare products and in directive 89/336/EEC which stipulates the technical parameters of products concerning their electromagnetic compatibility.

C) Means of assessing conformity

- Conformity was assessed by the procedure stated MDD 93/42/EEC, Annex VII.

D) Used norms

- The said product fulfills the requirements of these harmonized technical norms which were used for assessing of conformity: EN 60601-1, EN 60601-1-2, EN 12182 and EN 1441 (Risk Analysis).

Ing. Zbyněk Frolík
managing director